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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,435	03/29/2001	Michael Clare-Salzer	UF-160CD2	1769

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GAINESVILLE, FL 32606-6669

EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/821,435

**Applicant(s)**

CLARE-SALZER, MICHAEL

**Examiner**

David A Saunders, PhD

**Art Unit**

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 6 and 8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 4 is/are rejected.
- 7) ☒ Claim(s) 6 and 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## I. PROSECUTION STATUS

The amendment of 6/28/04 has been entered. Claims 1, 4, 6 and 8 are pending and under consideration.

The amendment has overcome the previously stated 102 rejections over Kuruvillu et al, Racke et al or Johns et al, as well as over Bentz et al.

Due to the finding of a new reference, the finality of the action of 3/2/04 is withdrawn and new grounds of prior art rejection are stated as follows.

## II. NEW GROUNDS OF REJECTION

Claims 1 and 4 are rejected under 35 U.S.C. 102((a) or (e)) as being anticipated by Wahl et al (5,449,688).

Wahl et al teach the treatment of inflammatory conditions including autoimmune diseases. The latter include diabetes mellitus (col. 2, line 34), which is the same as "insulin dependent diabetes." They teach treatment with various NOS inhibitors, including TGF – beta (col. 2, line 22). Wahl et al thus administer the compound instantly recited to treat the disease instantly recited.

The only other aspect of instant claim 1 that must be considered in relation to the reference is the claim recitation of "inhibiting the development of an autoimmune disease". Giving the broadest interpretation to this phrase, the examiner takes this to encompass "inhibiting the destructive sequelae of a chronic inflammatory immune response" (e.g. see Wahl et al at col. 1, lines 58-59; col. 6, lines 10-11), as well as "slowing of the progression" thereof (e.g. see Wahl et al at col. 6, line 26).

Even if a narrower interpretation were to be given to "inhibiting the development" as meaning the treating of a patient prone to diabetes (e.g. has an HLA type for predisposition thereto) but who shows no symptoms, then the reference would still apply. Note Wahl et al teach "prophylactic" (col. 4, line 28) treatment and "Prophylaxis" (col. 6, line 26); these terms convey the prevention of the disease in a manner consistent with "inhibiting the development" interpreted narrowly.

Further, it is noted that Wahl et al's teachings of inhibiting NOS are completely consistent with applicant's own teachings concerning the mechanism by which the instant invention operates (page 10, lines 14+). In any case, even if the mechanism contemplated by applicant were different from that of Wahl et al, anticipation would still be proper.

Regarding claim 4, note Wahl et al teach amino guanidine (col. 2, line 21) and also teach treatment with a combination of the contemplated compounds (col. 6, lines 34+).

Applicant's arguments with respect to claims 1, 4, 6 and 8 have been considered but are moot in view of the new ground(s) of rejection.

### III. REFERENCE OF INTEREST

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Johnston et al (6,403,562) show an invention consistent with instant claim 1. The '562 filing date is after applicant's effective date of 8/23/96.

Weiner et al WO 95/27500 teach treatment of diabetes by the oral administration of antigens such as glucagon, insulin and GAD, See, for example pages 18, 20 and

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22. They teach co-administration of the antigen with IL-4. The examiner finds no motivation to combine Weiner et al with Wahl et al, given the teachings of Weiner et al regarding the desirability of effecting localized production of TNF-beta. See page 4, lines 11-23.

#### IV. CONTACTS

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (571) 272-0849. The examiner can normally be reached on Monday to Thursday from 8 AM to 5:30 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/LR  
August 25, 2004

*David A. Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
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